Remarks

Claims 1, 5, 7, 15, and 19 are pending. Claims 1 and 5 have been amended. Claim 44 has been canceled. Support for the amendments to claims 1 and 5 can be found, for example, at page 9, lines 20-22 (wherein larger peptides may be used....since these polypeptides may be fragmented by suitable antigen-processing cells).

Rejection Under 35 U.S.C. § 112, first paragraph

Claims 1, 5, 15, 19, and 44 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

The claims have been amended to clarify the sequences flanking SEQ ID NO:1. The flanking sequences are those found in the native human WT 1 protein. The application, as originally filed, clearly illustrates that intact WT1 protein is processed by antigen presenting cells, thereby producing SEQ ID NO:1 (which is recognized by CTL). This indicated that SEQ ID NO.1 (RMFPNAPYL), in the context of WT1-derived flanking sequences can be3 cleaved by proteasomes and aminopeptidases to give rise to SEQ ID NO:1. Without having to perform undue experimentation, one of ordinary skill in the art would readily realize that long peptide precursors containing RMFPNAPYL and WT1 flanking sequences would be processed by HLA-A0201 antigen presenting cells and give rise to the RMFPNAPYL bound to HLA-A-0201.

The claims are directed to a peptide that contains the RMFPNAPYL sequence, wherein the N-terminal and/or C-terminal extensions are limited to the amino acid sequence of human WT-1 polypeptide. The peptides encompassed by the scope of the claims as pending can be readily identified without undue experimental burden.

Further features of the claimed invention have been clarified: the peptide is processed by HLA-A0201-positive antigen presenting cells (APC) to produce the HLA-A0201 bound RMFPNAPYL (support at page 9, lines 20-22). Shastri *et al.* clearly describe such processes (see Shastri *et al.* reference submitted with the amendment and response mailed on November 7, 2002).

The claimed peptides are easily identified by a person of ordinary skill in the art based upon the following structural features "common to the genus":

1) the sequence harbors the known sequence of human WT-1 polypeptide;

2) the sequence contains SEQ ID NO:1, N-terminal and C-terminal extension derived from the sequence of WT-1; and

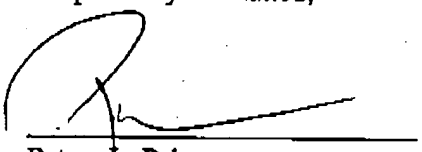
3) the sequence can be processed by HLA-A0201-positive antigen presenting cells (APC) resulting in the HLA-A0201 bound SEQ ID NO:1.

The instant description provides sufficient guidance for the peptide of the invention. The instant description provides sufficient guidance for the vaccine as presently claimed. The vaccine is not for any tumor cell, but for HLA-A0201-positive tumor cells that express WT1 aberrantly. These tumors constitute a highly specific selection. The applicants have enclosed a

reference showing that WT1 vaccination can protect mice against WT1 expressing tumor cells (Oka *et al., J. Immunol.*, 2000, Feb. 15; 164(4):1873-80).

Allowance of claims 1, 5, 7, 15, and 19 is respectfully solicited.

Respectfully submitted,



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